

## **REMARKS**

### **I. Status of the Claims**

Claims 1-3, 5-9, 12, 15-18, 21, 25, 26, 28-40, 42-46, 49 and 52-54 stand rejected under 35 U.S.C. Section 103(a) as being unpatentable over Konta et al. (*Significance of Discordant ST Alternans in Ventricular Fibrillation*) ("Konta"). Claims 4, 27 and 41 stand rejected under 35 U.S.C. § being unpatentable over Konta in view of U.S. Patent No. 6,965,797 to Pastore et al. ("Pastore"). Claims 10, 11, 22-24, 47 and 48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Konta in view of U.S. Patent No. 6,915,156 to Christini.

Reconsideration is respectfully requested in view of the amendments above and the remarks that follow.

### **II. The Rejections Under 35 U.S.C. § 103**

#### **A. Independent Claims 1, 18 and 38**

Claim 1 as amended recites a method for selectively initiating interventional therapy in a subject, including:

chronically detecting electrical activity in first and second cardiac regions in the subject;  
identifying discordant alternans in at least one component of the detected electrical activity based on a comparison of the electrical activity in the first and second cardiac regions; and  
initiating interventional therapy in the subject responsive to the identification of discordant alternans, wherein the electrical activity comprises an electrogram from internally implanted electrodes positioned in an internal chamber and/or vessel of the heart of the subject.

Claim 38 recites a computer program product corresponding generally to Claim 1.

Claim 18 recites a system for selectively initiating interventional therapy in a subject including:

a plurality of electrodes configured and sized to chronically detect electrical activity in first and second cardiac regions; and

a discordant alternans monitor operably associated with the electrodes, the discordant alternans monitor configured to identify discordant alternans in at least one component of the detected electrical activity based on a comparison of the electrical activity in the first and second cardiac regions; and to initiate interventional therapy in the subject responsive to the identification of discordant alternans, wherein the electrodes are configured to be internally implantable and positioned in an internal chamber and/or vessel of the heart of the subject.

In response to the reasons for patentability filed December 18, 2006, the Action takes the position that Konta discloses internally implanted electrodes because "despite the fact that the pericardium [in Konta] is exposed, any electrodes implanted on the heart are inherently internally implanted." See page 2 of the Action. Applicants respectfully submit that the exposed pericardium experiments in Konta are not internally implanted electrodes for chronically detecting discordant alternans because Konta clearly exposes the pericardium of the anesthetized dogs. However, in order to advance prosecution, Claims 1, 18 and 38 have been amended to recite that the electrodes are positioned in an internal chamber and/or vessel of the heart of the subject, as disclosed, for example, in Figure 4 of the current application.

Konta clearly does not disclose or suggest electrodes that are positioned in an internal chamber and/or vessel of the heart of the subject. As noted above, Konta discusses an experiment performed on dogs in which 60 electrodes are attached on the exposed pericardium of the dog. Konta, page 2185, col. 2. As discussed in the Specification at page 3, line 30 to page 4, line 3, electrical activity for successive cardiac cycles can be detected from a system chronically implanted in a subject, such as the electrodes A50, B51, C52, D53, E54, F55 and G56, which are positioned in an internal chamber and/or vessel of the heart of the subject. In contrast, the 60 electrodes of Konta are attached through a sock to the epicardium and to the area covering the region of the entire left and right ventricles when the pericardium of the dog is exposed. *Id.* Therefore, Konta does not disclose or suggest all of the recitations of Claims 1, 18 and 38 as required by § 103.

In addition, there is no motivation to modify Konta to use internally implanted electrodes positioned in an internal chamber and/or vessel of the heart of the subject. The dogs used in the experiment described by Konta all had induced acute myocardial ischemia.

Konta, page 2185, col. 2 and Abstract. Because Konta is focused on the discordance of ST alternans during acute myocardial ischemia and ventricular fibrillation, there is no motivation to chronically detect electrical activity in the heart using internally implanted electrodes positioned in an internal chamber and/or vessel of the heart of the subject as recited in Claims 1, 18 and 38.

Applicant submits that independent Claims 1, 18 and 38 are patentable at least for the reasons discussed above. Claims 2-12, 15-17, 21-37, 39-49, and 52-54 are patentable at least per the patentability of the claims from which they depend. Accordingly, Applicant requests that the rejections under § 103 be withdrawn.

In addition, various dependent claims are separately patentable for at least the reasons that follow.

**B. Claims 55-57**

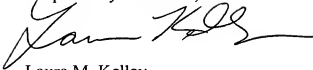
New Claims 55-57 depend from Claims 1, 18 and 38 and are patentable at least per the patentability of the claims from which they depend as discussed above. Claims 55-57 recite that the internally implanted electrodes are connected to internally implanted catheters. As noted above, Konta discusses that 60 electrodes are attached through a sock to the epicardium and to the area covering the region of the entire left and right ventricles when the pericardium of the dog is exposed. Applicants submit that nothing in Konta teaches or suggests using electrodes that are connected to internally implanted catheters, such as is shown in Figure 4 of the current application. Accordingly, Claims 55-57 are separately patentable and Applicants request an indication of same.

**III. Conclusion**

In view of the foregoing amendment and remarks, the Applicants respectfully request that all outstanding rejections to the claims be withdrawn and that a Notice of Allowance be issued in due course.

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Respectfully submitted,



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